032469-007



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Sam T. Lindholm et al.

Application No.: 10/759,244

Filing Date:

January 20, 2004

Group Art Unit: Unassigned

Examiner: Unassigned

Confirmation No.: Unassigned

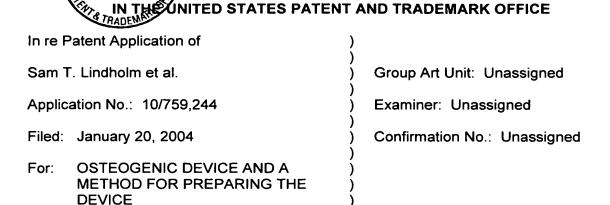
Attorney Docket No.

Title: OSTEOGENIC DEVICE AND A METHOD FOR PREPARING THE DEVICE

FIRST INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SIF:							
РТО	Enclosed -1449 for		FIRST entified paten			closure Statement and	accompanying form
	⋈ No a	dditional fee	for submissio	n of an IDS	is req	uired.	
	☐ The	fee of \$180.	00 (1806) as	set forth in 3	37 C.F	F.R. § 1.17(p) is also er	nclosed.
			er 37 C.F.R. §				
		atement unde 17(p) are also		1.97(e), and	d the	ree of \$180.00 (1806)	as set forth in 37 C.F.R.
	☐ Char	ge	to Depos	sit Account I	No. 02	2-4800 for the fee due.	
	☐ A ch	eck in the an	nount of	is	enclo	sed for the fee due.	
	☐ Char	ge	to cred	lit card. For	m PT	O-2038 is attached.	
	that may		by this paper,				C.F.R. §§ 1.16, 1.17 and sit Account No. 02-4800.
					Res	pectfully submitted,	
					BUF	RNS, DOANE, SWECK	ER & MATHIS, L.L.P.
Alex	Box 1404 andria, Vi) 836-662	rginia 22313	-1404		Ву	Duy	2 /
D-4-		0.0004				Deborah H. Yellin	
vare	: August	2, 2004				Registration No. 45,96	04



FIRST INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

The listed documents were previously made of record in prior Application Serial No. 09/125,963, filed November 24, 1998, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98, a copy of each of the listed documents, except those documents which were previously made of record in the prior application, is enclosed.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

I, the undersigned, hereby state that no item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three (3) months prior to the filing of this Information Disclosure Statement.

FIRST Information Disclosure Statement Application No. 10/759,244
Attorney's Docket No. 032469-007
Page 2

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

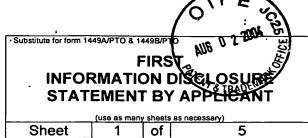
Date <u>August 2, 2004</u>

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620

VA 289880.1

By:

Registration No. 45,904



Complete if Known						
Application Number 10/759,244						
Filing Date	January 20, 2004					
First Named Inventor	Sam T. Lindholm et al.					
Examiner Name						
Attorney Docket Number	032469-007					

	U.S. PATENT DOCUMENTS						
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)			
	4,294,753		URIST	10-13-1981			
	4,434,094		SEYEDIN et al.	02-28-1984			
	4,455,256		URIST	06-19-1984			
	4,563,350		NATHAN et al.	01-07-1986			
	4,608,199		CAPLAN et al.	08-26-1986			
	4,627,982		SEYEDIN et al.	12-09-1986			
	4,681,763		NATHANSON et al.	07-21-1987			
	4,737,578		EVANS et al.	04-12-1988			
	4,761,471		URIST	08-02-1988			
	4,774,228		SEYEDIN et al.	09-27-1988			
	4,774,322		SEYEDIN et al.	09-27-1988			
	4,789,732		URIST	12-06-1988			
	4,798,885		MASON et al.	01-17-1989			
	4,804,744		SEN	02-14-1989			
	4,810,691		SEYEDIN et al.	03-07-1989			
	4,843,063		SEYEDIN et al.	06-27-1989			
	4,886,747		DERYNCK et al.	12-12-1989			
	4,968,590		KUBERASAMPATH et al.	11-06-1990			
	4,975,527		KOEZUKA et al.	12-04-1990			
	5,011,691		OPPERMANN et al.	04-30-1991			
	5,106,626		PARSONS et al.	04-21-1992			
	5,108,753		KUBERASAMPATH et al.	04-28-1992			
	5,187,076		WOZNEY et al.	02-16-1993			
	5,393,739		BENTZ et al.	02-1995			
	5,849,880		WOZNEY et al.	12-15-1998			
	5,631,142		WANG et al.	05-20-1997			
	6,190,880	-	ISRAEL et al.	02-20-2001			
	6,207,813		WOZNEY et al.	03-27-2001			
	6,245,889		WANG et al.	06-12-2001			

Examiner	Document	Kind Code (if known)	Country	Date of Publication	Translation	
Initials	Number			(MM-DD-YYYY)	Yes	No
	WO 88/00205		PCT	01-14-1988		
	WO 89/09787		PCT	10-19-1989		
	WO 89/09788		PCT	10-19-1989		
	WO 90/03733		PCT	04-19-1990		
	WO 91/02744		PCT	03-07-1991		
	WO 91/05802		PCT	05-02-1991		
	WO 91/18047		PCT	11-28-1991		
	WO 94/26322	, , , , , , , , , , , , , , , , , , , ,	PCT	11-24-1994		
	WO 95/24474		PCT	09-14-1995		
	WO 95/33830		PCT	12-14-1995		i
	41 30 546		DE	03-18-1993		i

Examiner		Date	- -
0:		-	
Signature		Considered	
	··· · · · · · · · · · · · · · · · · ·		

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

· Substitute for form 1449A/PTO & 1449B/PTO Complete if Known **Application Number** 10/759,244 FIRST **INFORMATION DISCLOSURE** Filing Date January 20, 2004 STATEMENT BY APPLICANT **First Named Inventor** Sam T. Lindholm et al. **Examiner Name** Sheet of **Attorney Docket Number** 032469-007

	NON-PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	AABOE, M., et al., "Healing of experimentally created defects: a review," BRITISH JOURNAL OF ORAL & MAXILLOFACIAL SURGERY (1995), pp. 312-318, vol. 33, Churchill Livingstone, Edinburgh, Scotland.
	AONO, AKI, et al., "Potent Ectopic Bone-Inducing Activity of Bone Morphogenetic Protein-4/7 Heterodimer," Biochemical and Biophysical Research Communication (1995), pp. 670-677, Academic Press, Inc.
	BODEN, S.D. et al., "Video-Assisted Lateral Intertransverse Process Arthrodesis," SPINE (1996), pp. 2689-2697, vol. 21, Lippincott Williams & Wilkins, Hagerstown, MD.
	BOSTROM, M., et al., "Use of Bone Morphogenetic Protein-2 in the Rabbit Ulnar Nonunion Model," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1996), pp. 272-282, no. 327, Lippincott Williams & Wilkins, Philadelphia, PA.
	CLEMENT, J.H., et al., "Bone morphogenetic protein 2 in the early development of Xenopus laevis," MECHANISMS OF DEVELOPMENT (1995), pp. 357-370, vol. 52, Elsevier Science, Limerick, Ireland.
	COOK, S.D., et al., "Recombinant Human Bone Morphogenetic Protein-7 Induces Healing in a Canine Long-Bone Segmental Defect Model," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1994), pp. 302-312, no. 301, J.B. Lippincott, Philadelphia, PA.
	COOK, S.D., et al., "The Effect of Recombinant Human Osteogenic Protein-1 on Healing of Large Segmental Bone Defects," THE JOURNAL OF BONE AND JOINT SURGERY, (1994), pp. 827-838, vol. 76-A, Amer. Vol., Boston, MA.
	COOK, S.D., et al., "In Vivo Evaluation of Recombinant Human Osteogenic Protein (rhOP-1) Implants As a Bone Graft Substitute for Spinal Fusions," SPINE (1994), pp. 1655-1663, vol. 19, Lippincott Williams & Wilkins, Hagerstown, MD.
	COOK, S.D., et al., "Effect of Recombinant Human Osteogenic Protein-1 on Healing of Segmental Defects in Non-Human Primates, BOSTON JOURNAL OF BONE AND JOINT SURGERY, (1995), pp. 734-750, American ed. 77(5), Boston, MA.
	COOK, S.D., et al., "Osteogenic Protein-1," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1996), pp. 29-38, no. 324, JB Lippincott, Philadelphia, PA.
	DAMIEN et al., "A Composite of Natural Coral, Collagen, Bone Protein and Basic Fibroblast Growth Factor Tested in a Rat Subcutaneous Model", Annales Chirugiae et Gynaecologiae, Supplementum, (1993) 207, 117-28.
	DART et al., "Transforming growth factors from a human tumor cell: characterization of transforming growth factor beta and identification of high molecular weight transforming growth factor alpha. Biochemistry, (1985 Oct 8) 24 (21) 5925-31.
	DUDLEY, A.T., et al., "A requirement for bone morphogenetic protein-7 during development of the mammalian kidney and eye," GENES & DEVELOPMENT (1995), pp. 2795-2807, vol. 9, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY.
	EHRNBERG, A., et al., "Comparison of Demineralized Allogeneic Bone Matrix Grafting (the Urist Procedure) and the Ilizarov Procedure in Large Diaphyseal Defects in Sheep," The JOURNAL OF BONE AND JOINT SURGERY, (1993), pp. 438-447, vol. 11, Orthopaedic Research Society, American Ed. Journal of Bone and Joint Surgery, Boston, MA.
	EINHORN, T.A., et al., "The Healing of Segmental Bone Defects Induced by Demineralized Bone Matrix," THE JOURNAL OF BONE AND JOINT SURGERY (1984), pp. 274-279, vol. 66-A, The Journal of Bone and Joint Surgery, Boston, MA.
	FANG, J., et al., "Stimulation of new bone formation by direct transfer of osteogenic plasmid genes," PROC. NATL. ACAD. Sci. (1996), pp. 5753-5758, vol.93 (USA), National Academy of Sciences, Washington, DC.
	FISCHGRUND, J.S., et al., "Augmentation of Autograft Using rhBMP-2 and Different Carrier Media in the Canine Spinal Fusion Model", JOURNAL OF SPINAL DISORDERS (1996), pp. 467-472, vol. 10, No. 6, Lippincott Williams & Wilkins, Hagerstown, MD.
	GAO, T.J., et al., "Microscopic evaluation of bone-implant contact between hydroxyapatite, bioactive glass and tricalcium phosphate implanted in sheep diaphyseal defects," BIOMATERIALS (1995), pp. 1175-1179, vol. 16, Oxford, England.
	GAO, T.J., et al., "Enhanced Healing of Segmental Tibial Defects in Sheep by a Composite Bone Substitute Comprised of Tricalcium Phosphate Cylinder, Bone Morphogenetic Protein and Type IV Collagen, JOURNAL OF BIOMEDICAL MATERIALS RESEARCH (1996), vol. 32, Interscience, Wiley, Hoboken, NJ.
	GAO, T.J., et al., "A coral composite implant containing bone morphogenetic protein repairs a segmental tibial defect in sheep: mechanics and immune assay," INTERNATIONAL ORTHOPAEDICS,, German Ceramics Society, Cologne, Germany.
	GAO, T.J., et al., "Comparative Study on Potential of Natural Coral and Tricalcium Phosphate Cylinders in Healing a Segmental Diaphyseal Defect in Sheep," BIOCERAMICS, pp. 199-204, vol. 8, German Ceramics Society, Cologne, Germany.
	GAO, T.J., et al., "Composite of Bone Morphogenetic Protein (BMP) and Type IV Collagen, Coral-Derived Coral Hydrozyapatite and Tricalcium Phosphate Ceramics," INTERNATIONAL ORTHOPAEDICS (ACCEPTED), Springer Verlag, Berlin, Germany.
	GAO, T.J., et al., "Bone Inductive Potential and Dose-Dependent Response of Bovine Bone Morphogenetic Protein Combined with Type IV Collagen Carrier," ANNALES CHIRURGIAE ET GYNAECOLOGIAE (1993), pp. 77-84, vol. 207, University of Tampere, Finland, University of Helsinki, Finland.
	GAO, TIE-JUN, "Bioactive Delivery System for Extracted Bone Morphogenetic Proteins" (1996), Acta Universitatis Tamperensis, ser A, vol. 511, Academic Dissertation, Tampere, Finland

Examiner	Date	
Signature	Considered	

· Substitute for form 1449A/PTO & 1449B/PTO Complete if Known **Application Number** 10/759,244 **FIRST INFORMATION DISCLOSURE** Filing Date January 20, 2004 STATEMENT BY APPLICANT **First Named Inventor** Sam T. Lindholm et al. **Examiner Name** Sheet of **Attorney Docket Number** 032469-007

	NON-PATENT LITERATURE DOCUMENTS							
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.							
	GERHART, T.N., et al., "Healing Segmental Femoral Defects in Sheep Using Recombinant Human Bone Morphogenetic Protein," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1993), pp. 317-326, no. 293, J.B. Lippincott Company, Philadelphia, PA.							
	HARRIS, E.L.V., "Concentration of the Extract", Chapter 3, In. Protein Purification Methods: A Practical Approach, Harris et al. (Eds.), September, 1989, IRL Press, Oxford, UK, page(s) 125-130.							
	HECKMAN, J.D., et al., "The Use of Bone Morphogenetic Protein in the Treatment of Non-Union in a Canine Model," THE JOURNAL OF BONE AND JOINT SURGERY (1991), pp. 750-764, vol. 73-A, The Journal of Bone and Joint Surgery, American Volume, Boston, MA.							
	HELM, G.A., et al., "Utilization of type I collagen gel, demineralized bone matrix, and bone morphogenetic protein-2 to enhance autologous one lumbar spinal fusion," J. NEUROSURGERY. (1997), pp. 93-100, vol. 86, Charlottesville, VA.							
	HOGAN, B.L.M., "Bone morphogenetic proteins: multifunctional regulators of vertebrate development," GENES & DEVELOPMENT (1996), pp. 1580-1594, vol. 10, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY.							
	HOLLIGER, E.H., et al., "Morphology of the Lumbar Intertransverse Process Fusion Mass in the Rabbit Model: A Comparison Between Two Bone Graft Materials — rhBMP-2 and Autograft," JOURNAL OF SPINAL DISORDERS (1996), pp. 125-128, vol. 9, Lippincott Williams & Wilkins, Hagerstown, MD.							
	HOLLINGER, J. & LEONG, K., "Poly(α-hydroxy acids): carriers for bone morphogenetic proteins," BIOMATERIALS (1996), pp. 187-194, vol. 17, Elsevier Science Limited, Butterworth-Heinemann, Oxford, England.							
	HOTZ, G. & HARR, G., "Bone substitute with osteoinductive biomaterials – current and future clinical applications," INT. J. ORAL MAXILLOFAC. SURG. (1994), pp. 413-417, vol. 23, Munksgaard, Copenhagen, Denmark							
	HU, Y.Y., "Experimental studies on reconstituted xenograft and its clinical application," Chinese Journal of Surgery, Vol. 31, no. 12, pp. 709-713, Zhonghua yi xue hui, Wai ke xue hui, Beijing, China.							
	JOHNSON, E.E. & URIST, M.R., "Distal Metaphyseal Tibial Nonunions Associated with Significant Bowing Deformity and Cortical Bone Loss: Treatment with Human Bone Morphogenetic Protein (h-BMP) and Internal Fixation," (1989), pp. 613-620, vol. 63, Nippon Seikeigeka Gakkai Zasshi, Japan.							
	JOHNSON, E.E., et al., "Repair of Segmental Defects of the Tibia with Cancellous Bone Grafts Augmented with Human Bone Morphogenetic Protein," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 249-257, no. 236, JB Lippincott, Philadelphia, PA.							
	JOHNSON, E.E., et al., "Bone Morphogenetic Protein Augmentation Grafting of Resistant Femoral Nonunions," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 257-265, no. 230, JB Lippincott, Philadelphia, PA.							
	JOHNSON, E.E., et al., "Autogeneic Cancellous Bone Grafts in Extensive Segmental Ulnar Defects in Dogs," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1989), pp. 254-265, no. 243, JB Lippincott, Philadelphia, PA.							
- · · -	JORTIK, LEENA, "Native Bone Morphogenetic Protein Purification and Action On Rat Skeletal Muscle Myoblast" (1998), Academic Dissertation Acta Universitatis Tamperensis 629, Tampere, Finland							
	JORTIKKA, LEENA, et al., "Partially Purified Reindeer (Rangifer Tarandus) Bone Morphogenetic Protein Has a High Bone-Forming Activity Compared With Some Other Artiodactyls," Clinical Orthopaedics and Related Research (1993), pp. 33-37, vol. 297, J. B. Lippincott Company							
	JORTIKKA et al., "Purification of monocomponent bovine bone morphogenetic protein in a water-soluble form", Annales Chirugiae et Gynacologiae, Supplementum, (1993) 207:25-30.							
	KATO, F., "Experimental study of chemical spinal fusion in the rabbit by means of bone morphogenetic protein," (1990), PubMed 2380596, Nippon Seikeigeka Gakkai Zasshi, Japan.							
	KIRKER-HEAD, CARL A., et al., "Long-Term Healing of Bone Using Recombinant Human Bone Morphogenetic Protein 2," Clinical Orthopaedics and Related Research (1995), pp. 222-230, vol. 318, Lippincott-Raven Publishers							
	KUBOKI, Y., et al., "Two Distinctive BMP-Carriers Induce Zonal Chondrogenesis and Membranous Ossification, Respectively; Geometrical Factors of Matrices for Cell-Differentiation," CONNECTIVE TISSUE RESEARCH (1995), pp. 219-226, vol. 32, Taylor & Francis, Philadelphia, PA.							
	LEE, S.C., et al., "Healing of large segmental defects in rat femurs is aided by RhBMP-2 in PLGA matrix," JOURNAL OF BIOMEDICAL MATERIALS RESEARCH (1994), pp. 1149-1156, vol. 28, Wiley Interscience, Hoboken, NJ.							
	LINDE, A. and HEDNER, E., "Recombinant Bone Morphogenetic Protein-2 Enhances Bone Healing, Guided by Osteopromotive e-PTFE Membranes: An Experimental Study in Rats," CALCIFIED TISSUE INT. (1995), pp. 549-553, vol. 56, Springer-Verlag, NY.							
	LINDHOLM, T.S., et al., "Response of Bone Marrow Stroma Cells to Demineralized Cortical Bone Matrix in Experimental Spinal Fusion in Rabbits," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1988), pp. 296-302, no. 230, JB Lippincott, Philadelphia, PA.							
	LINDHOLM, T.C., et al., "Bone Morphogenetic Proteins Regenerating Skull and Maxillo-Mandibular Defects," BONE MORPHOGENETIC PROTEINS (1996), pp. 149-155, R.G. Landes Company, Austin, TX.							
	LINDHOLM, T.S. and GAO, T.J., "Functional Carriers for Bone Morphogenetic Proteins," ANNALES CHIRURGIAE ET GYNAECOLOGIAE Supplementum, (1993), pp. 3-12, vol. 82, University of Helsinki, Helsinki, Finland.							

 Substitute for form 1 	FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Complete if Known				
	F	FIRS	ST .	Application Number	10/759,244	
INFO	RMATIC) NC	DISCLOSURE	Filing Date	January 20, 2004	
•				First Named Inventor	Sam T. Lindholm et al.	
	(use as many	sheets	as necessary)	Examiner Name		
Sheet	4	of	5	Attorney Docket Number	032469-007	

	NON-PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	LINDHOLM, TOM C., "Calvarial Reconstruction With Implants Of: Hydroxyapatite, Autogenous Bone Marrow, Allogeneic Demineralized Bone Matrix and Bovine Bone Morphogenetic Protein," Dissertation, University of Tampere and University of Turku, Finland (1995), pp. 8-280, Laatupaino-Yhtiöt Oy, Rauma, Finland
	LINDHOLM, T. SAM, M.D., Ph.D., "Tissue Engineering Intelligence Unit, Bone Morphogenetic Proteins: Biology, Biochemistry and Reconstructive Surgery" (1996), Chapters 3, 6, 12, 14, 15, 18, 19, R.G. Landes Company and Academic Press, Inc., Georgetown, Texas.
	LINDHOLM, T. S., et al., "Biological Activity of BMP to Type 1 and IV Collagen: A Preliminary Report," Department of Clinical Sciences, University of Tampere, pp. 45-50, Tampere, Finland.
	LOVELL, T.P., et al., "Augmentation of Spinal Fusion With Bone Morphogenetic Protein in Dogs," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1989), pp. 266-274, no. 243, JB Lippincott, Philadelphia, PA.
	MARTTINEN, A., et al., "Protein in a Water-Soluble Form," NEW TRENDS IN BONE GRAFTING (1991), pp. 40-43, Acta Universitatis Tamperensis, ser B vol 40, Tampere, Finland.
	MIYAMOTO, S. & TAKAOKA, K., "Bone Induction and Bone Repair by Composites of Bone Morphogenetic Protein and Biodegradable Synthetic Polymers," ANNALES CHIRURGIAE ET GYNAECOLOGIAE Supplement. 69-76, vol. 82, University of Helsinki, Helsinki, Finland.
	MUSCHLER, G.F., et al., "Evaluation of Human Bone Morphogenetic Protein 2 in a Canine Spinal Fusion Model," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1994), pp. 229-240, no. 308, J.B. Lippincott Company, Philadelphia, PA.
	NILSSON, O.S., et al., "Bone Repair Induced by Bone Morphogenetic Protein in Ulnar Defects in Dogs," THE JOURNAL OF BONE AND JOINT SURGERY, British Volume, (1986), pp. 635-642, vol. 68-B, London, UK.
	ODA, S., et al., "Ectopic bone induction in recombinant human bone morphogenetic protein-2 (rhBMP-2) combined with biphasic calcium phosphate (BCP)," (1996), The Journal of Stomatological Society, Japan.
	OGAWA et al., "Bovine bone activin enhances bone morphogenetic protein-induced ectopic bone formation", J. Biol Chem. (1992 Jul 15) 267 (20) 14233-7.
	ONO, I., et al., "Promotion of the Osteogenetic Activity of Recombinant Human Bone Morphogenetic Protein by Prostaglandin E ₁ ," BONE (1996), pp. 581-588, vol. 19, Elsevier Science Inc., NY.
	PAJAMÄKI, K.J.J., et al., "Bone Matrix in Rat Abdominal Muscle Pouch," University of Tampere, Tampere; Åbo Akademi University, Turku, University of Turku, Turku, Finland, pp. 132-138.
	PAJAMÄKI, K.J.J., et al., "Fibronectin and Collagen Types I and III in Aggressive Granulomatous Lesions Surrounding Hip Implants," University of Tampere, Tampere, Finland, pp. 300-304.
	PANGANIBAN, G.E.F., et al., "Biochemical Characterization of the <i>Drosophila dpp</i> Protein, a Member of the Transforming Growth Factor β Family of Growth Factors," Molecular and Cellular Biology (1990), pp. 2669-2677, vol. 10, American Society for Microbiology, Washington, DC.
	PETIT, J.C. & RIPAMONTI, U., "Tissue Segregation Enhances Calvarial Osteogenesis in Adult Primates," THE JOURNAL OF CRANIOFACIAL SURGERY (1994), pp. 34-43, vol. 5, Little, Brown & Co., Boston, MA.
	RAGNI, P. & LINDHOLM T.S., "Interaction of Allogeneic Demineralized Bone Matrix and Porous Hydroxyapatite Bioceramics in Lumbar Interbody Fusion in Rabbits," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1991), pp. 292-299, no. 272, JB Lippincott, Philadelphia, PA.
	RAGNI, P., et al., "Spinal Fusion Induced by Porous Hydroxyapatite Blocks (HA)," pp. 133-144, Italian Journal of Orthopaedics & Traumatology, Bologna, Italy.
	RAGNI, P.C. & LINDHOLM, T.S., "Bone Formation and Static Changes in the Thoracic Spine at Uni- or Bilateral Experimental Spondylodesis with Demineralized Bone Matrix (DBM)," pp. 237-252, Italian Journal of Orthopaedics & Traumatology, Bologna, Italy.
	RILEY, E.H., et al., "Bone Morphogenetic Protein-2," CLINICAL ORTHOPAEDICS AND RELATED RESEARCH (1996), pp. 39-46, no. 324, JB Lippincott, Philadelphia, PA.
	SAILER, H.F. & KOLB, E., "Application of purified bone morphogenetic protein (BMP) preparations in cranio-maxillo-facial surgery," JOURNAL OF CRANIO-MAXILLO-FACIAL SURGERY (1994), pp. 191-199, vol. 22, Churchill Livingstone, Edinburgh, Scotland.
	SAILER, H.F. & KOLB, E., "Application of purified bone morphogenetic protein (BMP) in cranio-maxillo-facial surgery," JOURNAL OF CRANIO-MAXILLO-FACIAL SURGERY (1994), pp. 2-11, vol. 22, Churchill Livingstone, Edinburgh, Scotland.
	SAMPATH, T.K. & REDDI, A.H., "Homology of bone-inductive proteins from human, monkey, bovine, and rat extracellular matrix," PROC. NATL. ACAD. Sci. USA (1983), pp. 6591-6595, vol. 80, National Academy of Sciences, Washington, DC.
	SAMPATH, T.K., et al., "Drosophila transforming growth factor β superfamily proteins induce endochondral bone formation in mammals," PROC. NATL. ACAD. SCI. USA (1993), pp. 6004-6008, vol. 90, National Academy of Sciences, Washington, DC.

Examiner	Date	
Signature	Considered	

 Substitute for form 1 	449A/PTO & 1	449B/P1	го	Complete if Known			
	1	FIRS	ST .	Application Number	10/759,244		
INFO	RMATI	ON I	DISCLOSURE	Filing Date	January 20, 2004		
STAT	EMEN	T BY	APPLICANT	First Named Inventor	Sam T. Lindholm et al.		
	(use as man	y sheets	as necessary)	Examiner Name			
Sheet	5	of	5	Attorney Docket Number	032469-007		

	NON-PATENT LITERATURE DOCUMENTS		
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	SAMPATH, T. KUBER, et al., "Bovine Osteogenic Protein Is Composed of Dimers of OP-1 and BMP-2A, Two Members of the Transforming Growth Factor-β Superfamily," The Journal of Biological Chemistry (1990), pp. 13198-13205, vol. 265, No. 22, The American Society for Biochemistry and Molecular Biology, Inc.		
	SANDHU, H.S., et al., "Evaluation of rhBMP-2 With an OPLA Carrier in a Canine Posterolateral (Transverse Process) Spinal Fusion Model," SPINE (1995), pp. 2669-2683, vol. 20, Lippincott-Raven Publishers.		
	SANDHU, H.S., et al., "Effective Doses of Recombinant Human Bone Morphogenetic Protein-2 in Experimental Spinal Fusion," SPINE (1996), pp. 2115-2122, vol. 21, Lippincott Williams & Wilkins, Hagerstown, MD.		
	SCHIMANDLE, J.H., et al., "Experimental Spinal Fusion With Recombinant Human Bone Morphogenetic Protein-2," SPINE (1995), pp. 1326-1337, vol. 20, Lippincott Williams & Wilkins, Hagerstown, MD.		
	SHEEHAN, J.P., et al., "Molecular Methods of Enhancing Lumbar Spine Fusion," NEUROSURGERY (1996),pp. 548-554, vol. 39.		
	STAEHLING-HAMPTON, K., et al., "Specificity of Bone Morphogenetic Protein-related Factors: Cell Fate and Gene Expression Changes in <i>Drosophila</i> Embryos Induced by <i>decapentaplegic</i> but not 60A," CELL GROWTH & DIFFERENTIATION (1994), pp. 585-593, vo. 5, American Association for Cancer Research, Philadelphia, PA.		
	SUN, Y., et al., "Repair of large cranial defect using allogeneic cranial bone and bone morphogenetic protein," PUBMED 7600438 (1995), Chinese Journal of Plastic Surgery and Burns, Beijing, China.		
	TORIUMI, D.M., et al., "Mandibular Reconstruction With a Recombinant Bone-Inducing Factor," ARCH OTOLARYNGOL HEAD NECK SURG (1991), pp. 1101-1112, vol. 117, American Medical Association, Chicago, IL.		
	URIST, M.R., et al., "Regeneration of an enchondroma defect under the influence of an implant of human bone morphogenetic protein," THE JOURNAL OF HAND SURGERY (1986), pp. 417-419, Vol. 11A, Churchill Livingstone, Secaucus, NJ.		
	URIST, M. R., et al., "Native Bone Morphogenetic Protein," University of Tampere Editorial Board (1992), pp. 27-39, Tampere, Finland.		
	URIST, M. R., et al., "Purification of bovine bone morphogenetic protein by hydroxyapatite chromatography," <i>Proc. Natl. Acad. Sci. USA</i> (1984), pp. 371-375, vol. 81.		
	URIST, MARSHALL R., "The search for and the discovery of bone morphogenetic protein (BMP)," Bone Grafts, Derivatives and Substitutes (1994), Chapter 17, pp. 315-362, Butterworth-Heinemann Ltd., Jordan Hill, Oxford, U.K.		
	VAN EEDEN, S.P. & RIPAMONTI, U., "Bone Differentiation in Porous Hydroxyapatite in Baboons Is Regulated by the Geometry of the Substratum: Implications for Reconstructive Craniofacial Surgery," PLASTIC AND RECONSTRUCTIVE SURGERY (1994), pp. 959-966, vol. 93, Lippincott Williams & Wilkins, Hagerstown, MD.		
	VILJANEN, V.V., et al., "Partial Purification and Characterization of Bone Morphogenetic Protein from Bone Matrix of the Premature Moose (<i>Alces alces</i>): Degradation of Bone-Inducing Activity during Storage," (1996), pp. 447-460, vol. 28, European Surgical Research, Karger, Basel, Switzerland.		
	VILJANEN, V.V., "Allogeneic and xenogeneic bone morphogenetic protein in skeletal reconstruction," (Academic Dissertation) UNIVERSITY OF TAMPERE (1997), Tampere, Finland.		
	VILJANEN, V. V., et al., "Xenogeneic moose (Alces alces) bone morphogenetic protein (mBMP)-induced repair of critical-size skull defects in sheep," International Journal of Oral Maxillofacial Surgery (1996), pp. 217-222, vol. 25, University of Tampere, Tampere and University of Helsinki, Helsinki, Finland.		
	VILJANEN, V. V., et al., "List of References On Demineralized Bone Matrix Induced Osteogenesis and Research of Bone Morphogenetic Proteins During the Period From 1951 Through 1995," Tissue Engineering Intelligence Unit, Bone Morphogenetic Proteins: Biology, Biochemistry and Reconstructive Surgery (1996), Appendix pp. 242-308, R. G. Land		
	WHARTON, K.A., et al., "Drosophila 60A gene, another transforming growth factor β family member, is closely related to human bon morphogenetic proteins," PROC. NATL. ACAD. SCI. USA (1991), pp.9214-9218, vol. 88, National Academy of Sciences, Washington, DC.		
	WOLFE M.W. & COOK, S.D., "Use of osteoinductive implants in the treatment of bone defects," MEDICAL PROGRESS THROUGH TECHNOLOGY (1994), pp. 155-168, vol. 20, Kluwer Academic, Boston, MA.		
	YASKO, A.W. et al., "The Healing of Segmental Bone Defects, Induced by Recombinant Human Bone Morphogenetic Protein (rhBMP-2)," The Journal of Bone and Joint Surgery, (1992), pp. 639-670, vol. 74-A, American Ed. Journal of Bone and Joint Surgery, Boston, MA.		

Examiner	Date	
Signature	Considered	